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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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05/12/2008

EXAMINER

JANG, CHRISTIAN YONGKYUN

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3735

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/523,743	Applicant(s) BADR, M SAFWAN	
	Examiner CHRISTIAN Y. JANG	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23-34 is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-10, 15-17 and 22 is/are rejected.
- 7) ☒ Claim(s) 7, 11-14, 18-21 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Priority

1. Applicant's claim of benefit of the filing date of Provisional Application 60/400,038 filed on 08/02/2002 is acknowledged by the examiner.

Information Disclosure Statement

2. The listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report have not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Objections

3. Claim 4 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 4 depends upon claim 3, which claims a three-term polynomial function. The computation of the derivative of a three-term polynomial function is inherently equivalent to the equation stated in claim 4, which, as the calculation of the derivative is claimed within independent claim 1, would be inherent within the language and scope of claim 3. Thus, claim 4 fails to further limit the subject matter of a previous claim.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. As to claims 5, the claim language states a "step of determining that a breath is inspiratory," with the result being considered "IFL" in the event that the derivative is greater or equal to zero. The specification shows that IFL stands for "Inspiratory Flow Limitation". It is unclear whether the step is determining that a breath is inspiratory or that an inspired breath is limited.

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7. As to claim 6, the claim language states a "step of determining a breath is inspiratory," with the result being considered "NIFL" in the event that the derivative is less than zero. The specification shows that "NIFL" stands for "Non-Flow Limited". It is unclear whether the step is determining that a breath is inspiratory or that an inspired breath is non-limited.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-4, 8-10, 15-17, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tham et al. (USP #6,068,602) in view of Starr et al. (USP #6,342,040).

10. As to claim 1, Tham teaches a method of measuring upper airway resistance of a human patient (Abs), the method comprising the steps of:

obtaining air pressure data from an air pressure data signal corresponding to a plurality of breathing cycles while the human patient is asleep (Abs; col. 2, lines 9-19; although Tham does not explicitly teach that the human patient is asleep, Tham teaches that the device is particularly useful in anesthesia applications. It is the examiner's position that a patient induced into anesthesia is in a state of sleeping);

obtaining air flow data from an air flow data signal corresponding to the plurality of breathing cycles while the human patient is asleep (Abs; col. 2, lines 9-19);

transferring the air pressure data and the air flow data to a processor (col. 3, lines 14-36);

storing the air pressure data and the air flow data in respective correlated storage regions of a matrix program system of the processor (col. 5, line 51-61);

segregating the air pressure data and the air flow data in the matrix program of the processor into corresponding breathing cycles of the human patient (col. 5, line 51-61);

computing normalized air pressure data to achieve a predetermined normalized air pressure value to correspond with a predetermined point for each breathing cycle of the human patient (Abs; col. 2, lines 20-34; col. 2, lines 50-60);

producing a correlation of the air flow data against normalized air pressure data (col. 3, lines 52-64);

curve-fitting onto the correlation of the air flow data against normalized air pressure data a curve corresponding to a predetermined multiple term mathematical function (col. 4, lines 42-49);

computing the value of the coefficients of the predetermined multiple term mathematical function (col. 5, lines 17-50).

Tham fails to teach of computing the derivative of the predetermined multiple term mathematical function. However, Starr teaches the a diagnostics device for monitoring a snoring patient during sleep (col. 3, lines 42-52), wherein a third order

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equation is used to fit the curves for a voltage-flow relationship (col. 11, lines 48-66), and a derivative calculated to determine a quantitative snore flow signal (col. 16, lines 36-56), which can be utilized to determine sleep apnea. In addition, the calculation of a derivative is well known in the art to determine properties of a mathematical function such as the rate of change. Hence, it would have been obvious to one of ordinary skill in the art to modify Tham with Starr to determine further properties of a determined function.

11. As to claim 2, Tham teaches the method wherein in said step of curve-fitting onto the correlation of the air flow data against normalized air pressure data a curve, the predetermined multiple term mathematical function is a quadratic function, $F(P)=AP_2+BP+C$, where A, B, and C are coefficients (col. 4, lines 39-49).

12. As to claim 3, Tham teaches the method wherein in said step of curve-fitting onto the correlation of the air flow data against normalized air pressure data a curve, the predetermined multiple term mathematical function is a three term polynomial function $F(P)=AP.\text{sup.}3+BP.\text{sup.}2+CP+D$, where A, B, C, and D are coefficients (col. 4, lines 39-49).

13. As to claim 4, although Tham fails to teach a step of computing the derivative, it would have been obvious to do so, as expounded above.

14. As to claim 8, Tham teaches a method of determining a flow-limiting characteristic of the upper airway of a human patient, the method comprising the steps of (Abs):

obtaining air pressure data from an air pressure data signal corresponding to a plurality of breathing cycles while the human patient is asleep (Abs; col. 2, lines 9-19);

obtaining air flow data from an air flow data signal corresponding to the plurality of breathing cycles while the human patient is asleep (Abs; col. 2, lines 9-19);

transferring the air pressure data and the air flow data to a processor(col. 5, line 51-61);

storing the air pressure data and the air flow data in respective correlated storage regions of a matrix program system of the processor (col. 5, line 51-61);

segregating the air pressure data and the air flow data in the matrix program of the processor into corresponding breathing cycles of the human patient (col. 5, line 51-61);

computing normalized air pressure data to achieve a predetermined normalized air pressure value to correspond with a predetermined point for each breathing cycle of the human patient (col. 2, lines 43-60; col. 4, lines 58-67); and

computing the flow-limiting characteristic of the upper airway of a human patient as a function of normalized air pressure data divided by corresponding air flow data (col. 4, lines 58-67).

15. As to claim 9, Tham teaches the method wherein the matrix program system is a spreadsheet program system, the air pressure data and the air flow data being arranged in respective spreadsheet columns correlated by rows (col. 5, line 51-61).

16. As to claim 10, Tham teaches the method wherein said step of computing normalized air pressure data comprises the further step of storing the normalized air

pressure data in a respective spreadsheet column correlated by rows into corresponding breathing cycles of the human patient (col. 5, line 51-61).

17. As to claim 15, Tham teaches the method wherein the air pressure data and the air flow data are sampled a plurality of times during each breathing cycle (col. 2, lines 43-60).

18. As to claim 16, Tham teaches the method wherein said step of computing the flow-limiting characteristic of the upper airway of a human patient is performed a corresponding plurality of times during each breathing cycle (col. 2, lines 43-60).

19. As to claim 17, Tham teaches the method wherein said step of computing the flow-limiting characteristic of the upper airway of a human patient is performed a corresponding plurality of times during each breathing cycle and during which the air flow data has a predetermined value (col. 5 line 62 to col. 6, line 8).

20. As to claim 22, Tham fails to teach the method wherein there is provided the further step of producing a data array corresponding to the flow-limiting characteristic wherein the normalized air pressure data corresponds to the x-axis and the air flow data corresponds to the y-axis. However, the plotting of data to a graph is well known in the art and would have been obvious for one of ordinary skill in the art to modify Tham with a graph plotting step to allow easier visualization of data.

Allowable Subject Matter

21. Claims 23-34 are allowed.

22. Claims 5 and 6 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action, as well

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as rewritten in independent form including all of the limitations of the base claim and any intervening claims.

23. Claims 5-7, 11-14, and 18-21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

24. The following is a statement of reasons for the indication of allowable subject matter:

25. As to claims 5 and 6, the prior art of record fails to teach a step wherein the derivative is used to determine whether breath is non-flow limited or flow limited.

26. As to claims 7 and 23, the prior art of record fails to teach a step of computing a resistance corresponding to the reciprocal of coefficient C.

27. As to claim 11, the prior art of record fails to teach that each breathing cycle of the human patient is determined in relation to the predetermined point thereof corresponding to the predetermined normalized air pressure value.

28. Claims 12-14 are indicated as allowable subject matter in that they depend upon claim 11.

29. As to claim 18, the prior art of record fails to teach a step of correlating air flow data and normalized pressure data to form a data correlation in an array, and the predetermined within a substantially linear portion of the data correlation.

30. Claims 19-21 are indicated as allowable subject matter in that they depend upon claim 18.

31. Claims 24-34 are allowable in that they depend upon claim 23.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTIAN Y. JANG whose telephone number is (571)270-3820. The examiner can normally be reached on Mon. - Fri. (8AM-5PM) EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/
Primary Examiner, Art Unit 3735

CJ
/C. Y. J./
Examiner, Art Unit 3735
4/22/08